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For VOLUNTARY repor
by health professionals of ad
events and product proble

Form Approved- OMB No. 2910-0291 Expires 12/31/96
See OMB statement on reverse

3121308-6-00-01

Page 1 of 1

A. Patient information

1. Patient Identifier	2. Age at time of event: 57 / Date of birth:	3. Sex	4. Weight
[redacted] In confidence		☒ female ☐ male	___ lbs or 80 kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death ___ (mo/day/yr)
- ☐ life-threatening
- ☐ hospitalization
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: ___

3. Date of event 8/11/98 (mo/day/yr)

4. Date of this report 8-21-98 (mo/day/yr)

5. Describe event or problem
BF was given Acetaminophen IV, and now has Grade 4 Hepatotoxicity due to high dose of acetaminophen.

REC'D.
AUG 24 1998
MEDWATCH CTU

6. Relevant tests/laboratory data, including dates
LFTs 8-12-98 AST 855 LFTs 8-13-98 AST 1315

[redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
NONE

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 Acetaminophen 30, 500 mg
#2

2. Dose, frequency & route used
#1 IV
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 8-11-98
#2

4. Diagnosis for use (indication)
#1 Ocular Melanoma- Metastatic
#2

5. Event abated after use stopped or dose reduced
#1 ☐ yes ☒ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
– –

10. Concomitant medical products and therapy dates (exclude treatment of event)
NONE

D. Suspect medical device

1. Brand name

2. Type of Device

3. Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ___

6.
model # ___
catalog # ___
serial # ___
lot # ___
other # ___

5. Expiration Date (mm/day/yr)

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mm/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mm/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & Address
[redacted] Cancer Center
[redacted] Ave.
[redacted]

phone #

2. Health professional? ☐ yes ☒ no

3. Occupation

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500 (1/96) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

MEDWATCH
HF-2

Taken By Telephone

CTU 98360